The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 25

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JANICE AU-YOUNG, PREETI LAL and OLGA BANDMAN

Appeal No. 2003-1817
Application No. 09/501,714

ON BRIEF

MAILED
AUG 31 2004
U.S. PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Before WILLIAM F. SMITH, SCHEINER, and GRIMES, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 45, 47-49, 52, 54-56 and 66-68. Claims 46 and 65 are pending and are objected to. Claims 43, 44, 50, 51, and 57-61 are also pending but have been withdrawn from consideration by the examiner. Claims 45, 52 and 54 are representative of the subject matter on appeal and read as follows:

45. An isolated polynucleotide encoding a polypeptide selected from the group consisting of:

a) an amino acid sequence of SEQ ID NO:1 or SEQ ID NO:3, and

b) a naturally-occurring amino acid sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1 or SEQ ID NO:3, and a polynucleotide complementary thereto.

52. An isolated polynucleotide comprising a sequence selected from the group consisting of:

a) a polynucleotide sequence of SEQ ID NO:2 or SEQ ID NO:4,

b) a naturally-occurring polynucleotide sequence having at least 90% sequence identity to the sequence of SEQ ID NO:2 or SEQ ID NO:4,

c) a polynucleotide sequence complementary to a), and

d) a polynucleotide sequence complementary to b).

54. A method for detecting a target polynucleotide in a sample, said target polynucleotide having a sequence of a polynucleotide of claim 52, the method comprising:

a) hybridizing the sample with a probe comprising at least 16 contiguous nucleotides comprising a sequence complementary to said target polynucleotide in the sample, and which probe specifically hybridizes to said target polynucleotide, under conditions whereby a hybridization complex is formed between said probe and said target polynucleotide or fragments thereof, and

b) detecting the presence or absence of said hybridization complex, and, optionally, if present, the amount thereof.

The examiner relies upon the following references:

Hillier et al., (Hillier Accession No. N93316), Database EST, Accession No. N93316 (Aug. 20, 1996)

Hillier et al., (Hillier Accession No. W63690), Database EST, Accession No. W63690 (Oct. 11, 1996)

Hillier et al., (Hillier Accession No. AA020916)Database EST, Accession No. AA020916 (Jan. 30, 1997)

Claims 45, 47-49, 52, 54-56 and 66-68 stand rejected under 35 U.S.C. § 112, first paragraph (written description). Claims 54 and 66 stand rejected under 35 U.S.C.

§ 103(a). As evidence of obviousness, the examiner relies upon Hillier Accession Nos. N93316, W63690, and AA020916. Claims 45-49 and 52 stand rejected under the judicially created doctrine of obviousness-type double patenting over the claims of U.S. Patent Nos. 5,922,567 or 6,001,598. We reverse the written description rejection and affirm the obviousness rejection and obviousness-type double patenting rejections. In addition, we make a new ground of rejection under 37 CFR § 1.196(b).

Discussion

1. Written description.

The examiner considers that claims 45, 47-49, 52, 54-56 and 66-68 do not comply with the written description requirement of 35 U.S.C. § 112, first paragraph, since:

> Allelic variants are alternate forms of a gene which have at least one mutation in the nucleotide sequence which may result in mRNAs (polypeptides) with altered function. With regard to a naturally-occurring human polynucleotide sequence variant, there is no description in the specification of any mutational site that exist in nature, and there is no description of how the structure of SEQ ID NOs: 2 or 4 relates to the structure of any allele including strictly neutral alleles. The general knowledge in the art concerning alleles does not provide any indication of how the structure of one allele is representative of unknown alleles. The nature of alleles is that they are variant structures, and in the present state of the art the structure of one does not provide guidance to the structure of others.

Examiner's Answer, page 6.

The Federal Circuit discussed the application of the written description requirement to inventions in the field of biotechnology in University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), stating that "[a] written description of an invention involving a chemical genus, like a description

of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials" Id. at 1567, 43 USPQ2d at 1405. The court also stated that

> a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. at 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

Claim 45 b) defines a genus of polynucleotides by way of two significant qualifiers. First, the polynucleotide of claim 45 b) must be "naturally occurring." Second, the polynucleotide of claim 45 b) must be "at least 90% identical to the

polynucleotide sequence of SEQ ID NO:1 or SEQ ID NO:3."[1] As explained in Lilly, a genus of polynucleotides can be described by a representative number of polynucleotides sharing common structural features which constitute a substantial portion of the genus. The examiner is correct in her analysis that claims 45 b) and 52 b) include so-called nonfunctional alleles. However, those nonfunctional alleles must be "naturally occurring" and be at least "90% identical to the polynucleotide sequence of SEQ ID NO:1 or SEQ ID NO:3."(claim 45 b) or "of SEQ ID NO:2 or SEQ ID NO:4" (claim 52 b)). In our view, these two limitations adequately describe the genus of polynucleotides encompassed by claim 45 b) and 52 b) without these claims further including a functional limitation.

We understand the examiner's concern that one may not recognize that a polynucleotide sequence having 90% identity with that of SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:2, or SEQ ID NO:4 is "naturally occurring." However, that concern is more properly raised under a rejection under 35 U.S.C. § 112, second paragraph, rather than the written description requirement of the first paragraph.

The written description rejection is reversed.

2. Obviousness.

We initially note that appellants state that the claims are grouped together for the purposes of this rejection. Appeal Brief, page 6. Accordingly, we shall decide the issues raised in the Examiner's obviousness rejection as they pertain to claim 54.

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[1] Claim 52 is similar to claim 45 but is directed to the polynucleotides of SEQ ID NO:2 or SEQ ID NO:4.

37 CFR § 1.192(c)(7). We also note that the three Hillier references relied upon by the examiner appear to be substantially similar. Thus, we shall consider the merits of the examiner's rejection as it is based upon Hillier accession N933160.

Claim 54 is directed to a method for detecting a target polynucleotide said to comprise the polynucleotide of claim 52 in a sample. To this end, a sample is hybridized with a probe comprising at least 16 contiguous nucleotides comprising a sequence complementary to said target polynucleotide in the sample. The probe will specifically hybridize to the target polynucleotide, if present, forming a hybridization complex. The presence or absence of the hybridization complex is an indication as to whether the sample contained the target polynucleotide.

The examiner has determined without dispute by appellants that Hillier accession N933160 describes a polynucleotide that has 99.2% identity to nucleotides 817-1298 of SEQ ID NO:2 of claim 52. Examiner's Answer, page 8. The examiner has concluded that it would have been obvious to a person of ordinary skill in the art to use any 16 contiguous nucleotides in the region of the polynucleotide sequence described in Hillier accession N933160 as a probe in a hybridization reaction to detect a target polynucleotide. Id., page 9.

Appellants argue that "claim [54] is directed to a method of detecting a target nucleotide having the sequence of a polynucleotide of claim 52" and that "[n]one of the applied art provides any description or recognition of a target polynucleotide having a sequence as set forth in claim 52." Appeal Brief, page 20.

Appellants' argument does not take into account that claim 54 explicitly reads upon a negative result, i.e., the probe comprising at least 16 contiguous nucleotides will not hybridize to any nucleotide sequence in the sample. This is seen in that claim 54 b) includes detecting the absence of a hybridization complex. Since appellants have not contravened the basic premise of the examiner's obviousness rejection, i.e., it would have been obvious to one of ordinary skill in the art to use a probe comprising at least 16 contiguous nucleotides based upon the polynucleotide sequence described in Hillier accession N933160 in a hybridization method, the performance of such a method that results in a negative result reads directly upon claim 54. Thus, the examiner's rejection can be sustained on this basis.

Second, we do not read claim 54 to be limited to only detecting the target polynucleotides comprising the polynucleotides recited in claim 52. Once a probe comprising at least 16 contiguous nucleotides is constructed based upon the polynucleotide sequence described in Hillier accession N933160, the use of that probe in a hybridization method will result in the hybridization complex being formed if the probe hybridizes to any polynucleotide sequence in the sample under the hybridization conditions used. Thus, an appropriately constructed probe based upon the polynucleotide sequence described in Hillier Accession No. N933160 will hybridize to a polynucleotide sequence such as that of Hillier accession N933160, that of SEQ ID NO:2 of this application or any other polynucleotide sequence having sufficient complementarity given the hybridization conditions used.

The examiner's obviousness rejection is affirmed.

3. Obviousness-type double patenting rejections

Appellants have acquiesced in the merits of these rejections by offering to file appropriate terminal disclaimers. Appeal Brief, page 21. Accordingly the double patenting rejections are affirmed.

New Ground of Rejection Under 37 CFR § 1.196(b)

Claims 55 and 56 are rejected under 35 U.S.C. § 103(a). Hillier accession N933160 is relied upon as evidence of obviousness.

As explained above, we agreed with the examiner's conclusion that the subject matter of claim 54 would have been obvious to one of ordinary skill in the art on the basis of Hillier accession N933160. Claims 55 and 56 further require that the probe comprise either at least 30 or 60 contiguous nucleotides. It also appears that the polynucleotide of Hillier N933160 contains stretches of at least 30 or 60 contiguous nucleotides as required by claims 55 and 56. See sequence comparison us-09-501-714-2.rst, July 1, 2000, page 6. Thus, claims 55 and 56 are rejected under this section of the statute for the reasons set forth above in regard to the extant obviousness rejection.

Time Period for Response

In addition to affirming the examiner's rejection of one or more claims, this decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b). 37 CFR § 1.196(b) provides, "[a] new ground of rejection shall not be considered final for purposes of judicial review."

Regarding any affirmed rejection, 37 CFR § 1.197(b) provides:

> (b) Appellant may file a single request for rehearing within two months from the date of the original decision . . . .

37 CFR § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (37 CFR § 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
>
> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

Should the appellant elect to prosecute further before the Primary Examiner pursuant to 37 CFR § 1.196(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If the appellant elects prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART; 196(b)

William F. Smith
Administrative Patent Judge

Toni R. Scheiner
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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) INTERFERENCES

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